

Rehabilitation Division

Smith & Nephew, Inc.
N104 W13400 Donges Bay Rd., P.O. Box 1005
Germantown, WI 53022-8205 USA
Telephone: 262 251 7840
Fax: 262 251 7758

Smith+Nephew

JUN - 6 2001

510(k) SUMMARY

The following is a summary of the Smith & Nephew RESTIM Electrical Muscle Stimulator 510(k) submission.

Rehabilitation Division
Smith & Nephew, Inc.
N104 W13400 Donges Bay Road
Germantown, WI 53022 - 8205
Phone: (262) 251-7840
Fax: (262) 251-7758

Printed Name: Cordell C. Hoffins

Signature: *Cordell C. Hoffins*

Title: Director of Quality Assurance and Regulatory Affairs

Date: 20 March / 2001

Device Description: The RESTIM electrical muscle stimulator consists of a microprocessor controlled electronic module which issues electrical muscle impulses in the form of direct current energy transfer via conductive pads. The pulse width, peak current amplitude and pulse repetition rate of the output are tightly controlled to close tolerance.

The RESTIM EMS unit has a single connector with multiple functions. This ensures that the connector can only be used for one function at any given time and avoid any risk to the patient. The connector connects the unit to the cable of the external power supply when the battery of the unit is being charged. The connector also connects the unit to the PC cable when the healthcare provider is setting the parameters of the unit or retrieving the usage data stored in the unit, and connects the unit to the cable of the electrodes when the unit is being used to deliver treatment to the patient.

A PC interface is provided and consists of a PC program. The PC program is a standalone application for the Microsoft Windows 95/98 operating system

Classification Name:	Stimulator, Muscle, Powered
Common Name / Usual Name:	Electrical Muscle Stimulator
Proprietary Name:	Smith & Nephew RESTIM
Classification:	21 CFR Part 890.5850 Powered Muscle Stimulator, Class II.
Performance Standards:	No Performance Standards for the Powered Muscle Stimulator are in effect.
Predicate Devices:	K951951 Empi FOCUS Model 795 unit. K940301 Biodex Medical Systems Compex 2 unit.
Indications (Intended Use):	<ol style="list-style-type: none"> 1. Relaxation of muscle spasms 2. Prevention or retardation of disuse atrophy 3. Increasing local blood circulation 4. Muscle re-education 5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis 6. Maintaining or increasing range of motion
Contraindications:	Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.
Testing:	<p>Risk Analysis per EN 1441.</p> <p>Unit is battery powered, the charger complies with UL 1310.</p> <p>Patient cable complies with 21 CFR 898 requirements and was tested to EN 60601-1, section 56.3.</p>
Substantial Equivalence:	<p>The Smith & Nephew RESTIM Electrical Muscle Stimulator is functionally equivalent, and its output characteristics fall well within those of the predicate devices, the K951951 Empi FOCUS Model 795 unit, and the K940301 Biodex Medical Systems Compex 2 unit. Electrodes offered for sale with the RESTIM device are K970426 Axelgaard "Valuetrodes" already on the market. Equivalence was based primarily on laboratory electrical testing and comparison to predicate devices.</p>

Comparison of features and principles of operation between the Smith & Nephew RESTIM Electrical Muscle Stimulator and predicate devices in the market via Section 510(k) of the "Act".

MANUFACTURER	Biodex Medical Systems, Inc.	Empi	Smith & Nephew
Model Number	Compex 2 model 925-100	Empi FOCUS	RESTIM
510(k) Number	K940301	K951951	To be assigned
Equipment classification	Hand held. Internally powered.	Hand held. Internally powered.	Hand held. Internally powered.
Output modality	Programmable pulse on/off times.	Programmable pulse on/off times and biphasic.	Fixed, single.
Power source	Rechargeable 7.2V NiMH battery pack or a.c. mains.	Primary cell, 9V PP3 battery.	Rechargeable NiMH 8.4V PP3 battery.
Recharge regime	In situ.	Replace battery.	In situ.
Patient connection	Type B. Patient connection possible during mains connected recharge.	Type BF. Isolated.	Type BF. Isolated. No patient connection is possible during recharge.
Current pulse regulation	Good.	Good.	Good.
Maximum output current	100mA	60mA	90mA
Load range	8ohm to 10Kohm	8ohm to 10Kohm	8ohm to open circuit
Maximum output voltage	+105V	+120V	+55V
Maximum phase charge	2.73 μC .	3.12 μC .	2.73 μC .
Peak current density *	14.14 mA/cm ² .	7.92 mA/cm ²	12.45 mA/cm ²
Maximum Power Density **	2.83x10 ⁻⁶ W/cm ² 2 Hz setting 0.011 W/cm ² 125 Hz setting	4.09x10 ⁻⁵ W/cm ²	4.29x10 ⁻⁶ W/cm ²
Pulse shape	Symmetric Biphasic.	Symmetric or asymmetric biphasic.	Asymmetric Biphasic.
Pulse pattern	Simple. Programmable repetition rate.	Simple. Programmable repetition rate.	Complex. One second repetition rate.
User set-up method	Memory card plus multiple front panel switches.	Multiple rotary dials.	Two switches for intensity increase/decrease.
User display	Graphic LCD panel with backlighting.	None.	2 digit LCD plus LED.

Low battery detect	Yes.	Partial.	Yes.
Connection error indication	Yes (open cct).	No.	Yes (open cct).
Treatment time	Programmable.	Selectable between 15 mins, 30 mins or continuous.	1 hour fixed.
Pulse width	Nominal 250 μ sec. User adjustable from 50 μ sec to 1 second.	Nominal 260 μ sec. User adjustable.	Nominal 250 μ sec. Can be set between 50 and 350 μ sec by the user.

* based on a 3cm diameter electrode (smallest available)

** taken at the maximum output current for all devices.

Conclusions:

The Smith & Nephew RESTIM Electrical Muscle Stimulator is designed to provide the same basic functions as the predicate units, the Compex 2, model 925-100 stimulator and the Empi FOCUS stimulator. It is intended to be used for the same indications. Smith & Nephew believes the RESTIM device is substantially equivalent in safety and efficacy to these predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 6 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Cordell C. Hoffins
Director of Quality Assurance and Regulatory Affairs
Smith & Nephew, Inc.
Rehabilitation Division
N104 W13400 Donges Bay Road
Germantown, Wisconsin 53022

Re: K003596

Trade Name: Smith & Nephew Restim Powered Muscle Stimulator
Regulation Number: 890.5850
Regulatory Class: II
Product Code: IPF
Dated: March 21, 2001
Received: March 22, 2001

Dear Mr. Hoffins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr Cordell C. Hoffins

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003596

DEVICE NAME: Restim Powered Muscle Stimulator

INDICATIONS FOR USE:

Indications for use for The Smith & Nephew, Inc. Restim Power Muscle Stimulator are:

1. Relaxation of muscle spasms;
2. Prevention of retardation of disuse atrophy;
3. Increasing local blood circulation
4. Muscle re-education;
5. Immediate post surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

William H. Brown
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

510(k) Number K003596

Concurrence of CDRH, Office of device regulation (ODE)

Prescription Use ✓

OR

Over-The-Counter-Use _____

(Per 21 CFR 801.109)

Optional Format 1-2-96)